IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8909

Bartle, J. July 10, 2012

Mary J. Daley ("Ms. Daley" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. John M. Daley, Ms. Daley's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In July, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Randall G. Johnson, M.D. Based on an echocardiogram dated July 13, 2004, Dr. Johnson attested in Part II of Ms. Daley's Green Form that she suffered from moderate aortic regurgitation and a reduced

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medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

ejection fraction in the range of 40% to 49%.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $522,266.[5]

In the report of claimant's echocardiogram, Dr. Johnson stated that Ms. Daley had "[m]oderate aortic insufficiency." Dr. Johnson, however, did not specify a percentage as to claimant's level of aortic regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view if the parasternal long-axis view is unavailable) is equal to or greater than 25% of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement §§ I.22. & IV.B.2.c.(2)(a). Dr. Johnson also determined that claimant's ejection fraction was "45 to 49 percent." An ejection fraction is considered reduced for purposes of an aortic valve claim if it is measured as less than 50%. See id. § IV.B.2.c.(2)(a)iii).

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4. Dr. Johnson also attested that claimant suffered from mild mitral regurgitation and New York Heart Association Functional Class I symptoms. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the aortic valve if he or she is diagnosed with moderate or severe aortic regurgitation and one of three complicating factors. See Settlement Agreement § IV.B.2.c.(2)(a). A reduced ejection fraction in the range of 40% to 49% is one of the complicating factors needed to qualify for a Level II claim.

In May, 2006, the Trust forwarded the claim for review by Robert L. Gillespie, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Gillespie concluded that there was no reasonable medical basis for Dr. Johnson's findings of moderate aortic regurgitation and a reduced ejection fraction in the range of 40% to 49%. Specifically, Dr. Gillespie stated that the "[aortic regurgitant] jet height was 15-20% of LVOTH." Dr. Gillespie also determined that claimant's ejection fraction was "50-55%." In support of this conclusion, Dr. Gillespie stated that:

> Endocardial borders not well enough defined to measure a quantitative [left ventricular ejection fraction]. The measurement obtained on tape is not [consistent with] the qualitative analysis, most likely secondary to poor border detection. Additionally, this measurement is in the setting of a large pericardial effusion.

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying Ms. Daley's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant argued that the

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Daley's claim.

attesting physician's conclusions should be accepted unless they are "extreme or excessive." Claimant also asserted that "[q]uantifying the level of regurgitation shown on an echocardiogram is inherently subjective."[7] In addition, Ms. Daley contended that the Trust did not properly apply the "reasonable medical basis" standard established in the Settlement Agreement because the auditing cardiologist simply substituted his own opinion for that of the attesting physician.[8] Further, claimant argued that an August 28, 2006 echocardiogram demonstrating "moderate(2+) aortic regurgitation" supported the attesting physician's finding of moderate aortic regurgitation. Finally, as to her ejection fraction, claimant asserted that "it is impossible for a 1% difference of opinion to have 'no reasonable medical basis,'" and that "up to 10% inter-reader variability is the norm."[9]

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7. In support of this argument, claimant submitted excerpts of depositions of five (5) physicians from other proceedings. None of the testimony submitted by claimant, however, specifically addressed Ms. Daley's echocardiogram.

8. In support of this assertion, claimant relied on the auditing cardiologist's conclusion that Ms. Daley's October 17, 1997 echocardiogram revealed moderate aortic regurgitation.

9. Claimant also contended that the Trust should ensure that its auditing cardiologists do not have any "biases" against claimants. As there is no evidence of any "bias," this issue is irrelevant for resolution of this claim. Similarly, claimant referenced, without any substantive discussion, a number of filings in MDL 1203. As claimant has not attempted to establish how these filings entitle her to Matrix Benefits, they are not

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The Trust then issued a final post-audit determination again denying Ms. Daley's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Daley's claim should be paid. On October 25, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7488 (Oct. 25, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on September 3, 2008, and claimant submitted a sur-reply on October 3, 2008. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate aortic regurgitation and a reduced ejection fraction in the range of 40% to 49%. See id. Rule 24.

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9. (...continued)
pertinent to the disposition of this show cause claim.

Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Daley reasserts the arguments that she made in contest. Claimant also contends that it is not uncommon for two cardiologists to review the same echocardiogram and to find different levels of regurgitation and, as such, "[n]either diagnosis is correct or incorrect; both fall within the realm of having a 'reasonable medical basis.'"[10]

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately contest Dr. Gillespie's findings that claimant had only mild aortic regurgitation and an ejection fraction in the range of 50% to 60%. Despite the opportunity in the contest

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10. Claimant also asserts that the requirements of a Level II claim for benefits do not limit a finding of moderate aortic regurgitation to only the parasternal long-axis view of an echocardiogram (or the apical view if the parasternal long-axis view is not available). As claimant has not provided any submission from either her attesting physician or an expert that moderate aortic regurgitation was present even in the apical view of her July 13, 2004 echocardiogram, we need not address this argument.

period to present additional evidence in support of her claim, Ms. Daley rests only on Dr. Johnson's check-the-box diagnoses on her Green Form. She does not adequately refute or respond to the auditing cardiologist's specific determinations that the "[aortic regurgitant] jet height was 15-20% of LVOTH," and that the "[q]ualitative [left ventricular ejection fraction] was 50-55%. Endocardial borders not well defined enough to measure a quantitative [left ventricular ejection fraction]."[11] Mere disagreement with the auditing cardiologist without identifying specific errors is insufficient to meet a claimant's burden of proof.[12]

We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more

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11. Claimant's reliance on her October 17, 1997 and August 28, 2006 echocardiograms to establish a reasonable medical basis for representations based on her July 13, 2004 echocardiogram, the echocardiogram of attestation, also is misplaced.

12. For this reason as well, we find that this is not merely conflicting "subjective" diagnoses between the attesting physician and the auditing cardiologist. Nor has Dr. Gillespie merely substituted his opinion for that of the attesting physician. Instead, Dr. Gillespie found that there was no reasonable medical basis for the attesting physician's findings of moderate aortic regurgitation and a reduced ejection fraction in the range of 40% to 49%. Neither claimant nor claimant's attesting physician refutes or responds to these findings.

stringent than claimant contends and one that must be applied on a case-by-case basis. Here, Dr. Gillespie determined in audit, and Ms. Daley does not adequately dispute, that the attesting physician's finding of moderate aortic regurgitation was unreasonable. Specifically, Dr. Gillespie measured claimant's JH/LVOTH to be less than 20% and determined claimant's ejection fraction was in the range of 50% to 55%. Contrary to claimant's argument, Dr. Gillespie properly applied the reasonable medical basis standard established under the Settlement Agreement.

Similarly, we are not persuaded that there must be a reasonable medical basis for claimant's attesting physician's finding of a reduced ejection fraction in the range of 40% to 49% because, as compared to the finding of the auditing cardiologist, there is only a "slight" difference in the respective findings. In making this argument, claimant ignores that the auditing cardiologist specifically concluded that claimant's ejection fraction did not meet the criteria required by the Settlement Agreement. Nothing in the Settlement Agreement allows a claimant to recover Matrix Benefits where she relies on a measurement merely close to that mandated by the terms of the Settlement Agreement. To conclude otherwise would allow claimants who do not have a qualifying reduced ejection fraction to receive Matrix Benefits.

Finally, we reject claimant's inter-reader variability argument concerning Dr. Gillespie's conclusion as to her ejection fraction. The concept of inter-reader variability is encompassed in the reasonable medical standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's finding of a reduced ejection fraction in the range of 40% to 49% cannot be medically reasonable where the auditing cardiologist concluded that claimant's ejection fraction was 50% to 55%. Neither claimant nor her attesting physician rebutted this specific finding. Rather, claimant simply argues that the court should accept a difference of "up to 10%" for the complicating factor of a reduced ejection fraction. Accepting claimant's argument, however, would allow a claimant, for purposes of an aortic valve claim, to assert the presence of a qualifying reduced ejection fraction even where the ejection fraction was as high as 59%. This result would render meaningless the standards established in the Settlement Agreement.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate aortic regurgitation and a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Daley's claim for Matrix Benefits and related derivative claim submitted by her spouse.